

REMARKS

Claims 1-9 are rejected in the Action under 35 U.S.C. 102(b) as being anticipated by each of Kai et al., U.S. Patent Application Publication No. 2002/0061338 ("Kai '338"), and Kai et al., U.S. Patent No. 6,464,977 ("Kai '977").

Kai '338 is identified by the Office as disclosing a solid double preparation type sodium bicarbonate solid preparation for dialysis which is a mixture of a first composition composed of core particles including sodium chloride and a coating layer of one or more electrolytes and a second composition comprised of a sugar and an acid. The first composition is stated to have an average particle diameter of the granules of 300 to 1700 microns and is mixed with the second composition. The Office notes that the specification of Kai '388 discloses a limited list of acids including acetic acid, hydrochloric acid, lactic acid, citric acid and oxalic acid as the acid of the second composition.

Kai '388 is also identified by the Office as disclosing two different methods of making the solid preparation. The first method includes a first step of spraying an aqueous solution of electrolyte containing, for example, magnesium chloride, onto core particles of sodium chloride and then drying; a second step of spraying core particles of a sugar to obtain a second composition;

and a third step of mixing the first and second compositions with an acid to obtain a solid preparation.

The second method is stated to differ from the first method in that the first composition is mixed with an acid first and then mixed with the second composition comprising the sugar to obtain a solid preparation for dialysis.

It is the position of the Office that since the materials are the same and the method steps of spraying and drying are the same as those claimed in the present application then the method of Kai '338 inherently granulates the material.

Kai '977 is cited as anticipating claims 1-3, 6 and 7 and is identified as disclosing a sodium bicarbonate solid preparation for dialysis comprising a solid preparation comprising a mixture of core particles of sodium chloride coated with one or more electrolytes such as magnesium chloride and particles of a second composition and an acid. The acid can be acetic acid, hydrochloric acid, lactic acid, or citric acid or oxalic acid. The granulated particle size is 300 to 1700 microns.

The claims of the present application have been amended to overcome the 35 U.S.C. § 102 rejections. Specifically, the claims have been amended to recite the solid pharmaceutical preparation for dialysis and the process for producing the solid pharmaceutical

preparation for dialysis of the present invention in terms that exclude sugar from the solid pharmaceutical preparation (A) of the claimed solid pharmaceutical preparation. The solid preparations for dialysis of each of Kai '338 and Kai '977 require a sugar in combination with particles of a first composition containing one or more electrolytes, and with an acid.

Removal of the 35 U.S.C. § 102 rejections of the claims is in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated August 11, 2008.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension and any additional required fees may be charged to our Deposit Account No. 111833.

Respectfully submitted,  
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